

## REMARKS

The present application contains claims 1-85, the status of which is as follows:

(a) Claims 2-4, 7, 12, 14-15, 31, 34, 37, 39, 41-42, 46-48, 51, 53, 57-58, 73, 76, 78, 80, 82-83, and 85 are as originally filed.

(b) Claims 11, 13, 56, 79, 81, and 84 were previously amended.

(c) Claims 1, 5-6, 8, 10, 30, 32-33, 35-36, 38, 40, 43-45, 49-50, 52, 55, 72, 74, 75, and 77 have been currently amended.

(d) Claims 9, 16-29, 54, and 59-71 have been canceled without prejudice.

No new matter has been added. Reconsideration is respectfully requested.

### *Rejections under 35 U.S.C. 102(b) over KenKnight*

Claims 1-8, 11-22, 25-35, 38-53, 56-66, 69-78, and 81-85 were rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,797,967 to KenKnight.

While not necessarily agreeing with the rejection of independent claims 1 and 45 and their dependent claims, the Applicant has amended these independent claims as described hereinbelow, in order to expedite the issuance of a patent on subject matter believed to be allowable.

While not necessarily agreeing with the rejection of independent claims 16 and 59 and their dependent claims, the Applicant has canceled these claims in order to expedite the issuance of a patent on subject matter believed to be allowable.

The Applicant respectfully traverses the rejection of independent claims 30 and 72. The Examiner argued that KenKnight teaches "supplying energy that is less than 1 joule" in col. 2, lines 58-67 (p. 4 of the Office Action).

The Applicant submits that a central feature of claims 30 and 72 is entirely absent from KenKnight, and from US Patent 5,522,853 to Kroll, which KenKnight is summarizing on col. 2, lines 58-67. Claims 30 and 72 recite defibrillating the heart by applying "an electrical signal to the heart with a total energy of no more than about 1 joule." In contrast, KenKnight and Kroll describe applying "a *series* of 'recruitment' pulses on the order of approximately 1 Joules [sic] *per pulse* . . . thus successively capturing regions of fibrillating tissue and thus coordinating activation wavefronts such that *a defibrillation pulse can be timed to successfully convert the fibrillation at a lower energy level*" (KenKnight, col. 2, line 62 – col. 3, line 1, emphasis added). (In fact, the pulses described by Kroll are approximately 0.9 Joule; col. 8, line 66.) The pulses of KenKnight and Kroll having the energy of about 1 joule are not defibrillation pulses at all, but are instead "recruitment" pulses that prepare the heart for subsequent defibrillation by a true defibrillation pulse.

The signal applied by KenKnight and Kroll has a total energy of at least 3 joules, and in the principal embodiment illustrated in Kroll, has a total energy of at least 8 joules. The total energy of at least 3 joules includes:

- the "series of 'recruitment' pulses on the order of approximately 1 Joules [sic] per pulse" includes at least 2 pulses, as indicated by the use of the word "series" and the "pulses" in the plural, for a total energy of at least 2 joules; and

- the subsequent "defibrillation pulse" has an energy of at least 1 joule, as described in Kroll: "the present invention as shown in FIG. 4 delivers a multiple, discontinuous pulse waveform 40 that is comprised of a series of smaller recruitment pulses 42 delivered prior to delivery of a *larger defibrillating pulse 44*" (Kroll, col. 6, lines 44-47, emphasis added).

The total energy of at least 8 joules in the principal embodiment illustrated in Kroll includes:

- the "series of 'recruitment' pulses" includes 6 pulses in Fig. 4 of Kroll, for a total energy of at least 6 joules; and
- the subsequent "defibrillation pulse" has an energy of at least 2 joules, as can be seen in Fig. 4 of Kroll by comparing the illustrated strength of defibrillating pulse 44 with that of recruitment pulses 42.

In contrast, claims 30 and 72 recite that the applied signal has a total energy of no more than about 1 joule, which is substantially less than the total energy described in KenKnight and Kroll. The Applicant thus submits that claims 30 and 72 are neither anticipated by, nor obvious in light of, KenKnight or Kroll. Claims 31-44 and 73-85 directly or indirectly depend from claims 30 and 72, respectively, and are also allowable, being of narrower scope than the allowable independent claims from which they depend.

*Rejections under 35 U.S.C. 103(a) over KenKnight in view of Pless*

Dependent claims 9-10, 23-24, 36-37, 54-55, 67-68, and 79-80 were rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight further in view of US Patent 5,489,293 to Pless et al. Although not necessarily agreeing with the rejections of claims 23-24 and 67-68, the Applicant has canceled these claims, as described above, in order to expedite issuance of a patent on subject matter believed to be allowable. Also as described above, the Applicant submits that claims 36-37 and 79-80 are allowable, because they depend from claims 30 and 72, respectively, which the Applicant believes to be allowable.

The Applicant respectfully traverses the rejection of claims 9 and 54. The Applicant has canceled these claims and incorporated the features thereof into independent claims 1 and 45, respectively. The Examiner argued that "KenKnight discloses the defibrillator substantially as claimed, but does not specifically disclose that the pulses are less than 100W. Pless discloses a staged energy storage system for an implantable device capable of delivering a 5 Watt, 1 Joule pulse every 100ms (Column 6, lines 31-43). . . . it would have been obvious . . . to have provided the defibrillator of KenKnight with the pulses less than 100W as taught by Pless to have provided defibrillation pulses with a low voltage power source, in order to maximize the life of the implantable device's battery" (pp. 4-5 of the Office Action).

The Applicant respectfully submits that the Examiner has not accurately characterized the power of the pulses applied by Pless. The 5 watts mentioned by Pless and cited by the Examiner (col. 6, line 41; see also col. 6, line 5) is the power at which HV capacitor 59 is recharged by HV charge block 58, and not the power at which HV capacitor 59 delivers pulses to the patient: ". . . recharging pulses of 0.5 joules (5 watts for 100 milliseconds)" (col. 6, lines 41-42, emphasis added). The pulses applied to the

patient have a power of substantially greater than 100 W, as can be calculated from Table 1 (col. 6, lines 45-58). For example, "Shock Number 1" has a "Shock Energy" of 1 joule, and a "Pulse Width" of 3.3 msec, which result in a total power of 303 W (1 joule / 0.0033 sec). Similarly, Shock Number 10, which has the lowest illustrated power, has a power of 196 W (1 joule / 0.0059 sec).

Furthermore, even if, for the sake of argument, it were to be assumed that Pless teaches a peak power less than about 100 W, it would not be obvious to combine Pless's techniques with those of KenKnight. As stated explicitly by KenKnight, one of the goals of his invention is to reduce the strength of the applied defibrillation: "Regardless of how the invention is described, the advantage of the invention is that the strength (voltage and/or energy) required for successful defibrillation by the first defibrillation-level shock is reduced" (col. 3, lines 58-61). With this goal in mind, KenKnight presumably describes the lowest strength signal that he believes to be effective using the techniques of his invention. The fact that a lower strength signal may have been used by another, such as Pless, for a different defibrillation technique, is of no relevance to KenKnight. There is no basis in KenKnight to believe that KenKnight's techniques would work with the purported lower strength signal of Pless, and KenKnight does not teach using such a strength, despite his stated goal of achieving a reduced strength signal.

The Applicant thus submits that claims 1 and 45, as amended, are now in a condition for allowance. Claims 2-8 and 10-15 directly or indirectly depend from claim 1, and claims 46-53 and 55-58 directly or indirectly depend from claim 45, and are also allowable, being of narrower scope than the allowable independent claims from which they depend.

*Claim rejections under 35 U.S.C. 112*

Claims 6, 8, 19-20, 22, 32-33, 35, 49-50, 52, 62-63, 65, 74-75, and 77 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "and comprising." The Examiner argued that this language "expands the previous claim instead of further limiting it." Although the Applicant disagrees with the grounds of rejection, the Applicant has amended these claims as suggested by the Examiner in order to expedite prosecution. (The Applicant respectfully submits that adding an element to a claim *per se* narrows the claim, regardless of whether "and comprising" or "further comprising" is used. These phrases thus have the same meaning.)

*Additional amendments to the claims*

Claims 36, 38, 40, 43, 44, 67, and 69 have been currently amended to change their respective claim dependencies. All of the new claim dependencies were recited (using multiple dependencies) in the application as originally filed, so no new matter has been added by these amendments.

Claims 1, 30, 45, and 72 have been amended to more positively recite the step of defibrillation. Claims 1 and 30 have further been amended to add the step of determining that fibrillation is occurring. This amendment finds support throughout the specification as filed, including near the beginning of the Summary of the Invention: "When it is determined that fibrillation or other dangerous arrhythmic activity is occurring in the heart, the control unit administers a signal. . ." (p. 2, lines 6-8).

*Specification*

The abstract was objected to because the abstract was not in narrative form and not on a separate sheet. A new abstract is provided hereinabove that is in narrative form and on a separate sheet.

The Applicant believes the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection and objection raised by the Examiner. In view of these amendments and remarks, the Applicant respectfully submits that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,

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